

## **REMARKS**

Claims 1-7, 9-11, 14, and 23-35 are pending in the application with new claim 35 added herein. New claim 35 is supported at least by page 3, lines 3-5; page 4, lines 1-3, 30-35; and page 5, lines 16-18 of the published PCT application.

Claims 1-7, 9-11 and 14 are rejected under 35 U.S.C. 112, first paragraph, as lacking a written description in the specification. Applicant requests reconsideration.

Page 2 of the Office Action alleges it is unclear how the “flexible openwork structure ... selected from the group consisting of knitted wire and chainmail” will be able “to allow movement of liquid through the prosthetic valve only in one direction,” as set forth in claim 1. Applicant traverses and asserts that the prosthetic valve is able to operate in the manner claimed under the control of those of ordinary skill using known techniques for prosthetic valve installation. Applicant further notes that the claims are intended to relate to the valve as manufactured and sold, and not necessarily to the valve actually in use. Still further, without admitting to the propriety of the rejection, Applicant herewith presents a timely filed declaration dated September 3, 2010 by the inventor, who is a practicing cardiothoracic surgeon and, therefore, is able to comment on the rejection with considerable authority.

Briefly, the valve can be used as if any apertures in the knitted wire or chainmail are very small, i.e. a very fine mesh. The valve may be sold precoated with a degradable coating, or the valve may be sold uncoated and

coated immediately before use by the surgeon inserting the valve. A surgeon using one of the claimed valves would have the option of selecting a fine mesh valve, or selecting a precoated valve, or selecting a larger mesh valve and coating it with the valve recipient's own blood immediately before use. It should be noted that this latter option, although it sounds cumbersome, could well be attractive in a number of applications because it removes the risk of side effects of the degradable coating. At least for such reasons, Applicant asserts that claim 1 is patentable. Claim 10 and the claims depending from claims 1 and 10 set forth similar limitations and are patentable for similar reasons. Applicant requests withdrawal of the rejection in the next Office Action.

Claims 23-34 are rejected under 35 U.S.C 102(e) as being anticipated by DiMatteo (US Patent No. 7,267,686). Applicant requests reconsideration.

Claim 23 sets forth a prosthetic valve having a flap valve that includes at least one flap consisting of a flexible openwork structure of a medically acceptable metal coated with a degradable sealing material. The flexible openwork structure is selected from the group consisting of knitted wire and chain mail. Pages 2-3 of the Office Action allege that DiMatteo discloses every limitation of claim 1. Applicant traverses.

As stated in column 7, lines 34 et seq., the DiMatteo valve has several valve leaves 40 that include a valve leaf frame 52 defining a leaf frame aperture 62 sealed by a valve leaf cover 80. As stated in column 10, lines 21-49, leaf cover 80 is sufficiently thin and pliable so as to permit radially-collapsing the valve for delivery by catheter to a location within a body lumen.

Leaf cover 80 may be a fluid-impermeable, biocompatible, non-thrombogenic material positioned on leaf frame 52 and other components of a trellis 24 so as to seal the leaf frame aperture 62. Leaf cover 80 seals leaf frame aperture 62 at least between component legs 54 and 56 of leaf frame 52 and hinge line 22. The material of leaf cover 80 may be Polyethylene (PE), Pellethane, Urethane, bovine pericardial tissue, a surgically-useful textile (such as Dacron, Polyethylene terephthalate (PET), silk, Rayon, or the like), or a surgically-useful polymeric material (such as polytetrafluoroethylene (PTFE)).

It is readily apparent from columns 7-10 and corresponding Figs. 1-5 of DiMatteo that valve 10 includes a trellis 24 that has an open construction. Leaf cover 80 is secured over and moves with leaf frame 52, which forms a part of trellis 24. In all DiMatteo embodiments, leaf frame 52 and cover 80 together form valve leaf 40. DiMatteo fails to disclose any valve flaps consisting of cover 80. DiMatteo thus fails to suggest at least one flap consisting of a flexible openwork structure of knitted wire or chainmail, as set forth in claim 23.

Page 3 of the Office Action refers to column 4, lines 33-44 and Figs. 108 as allegedly disclosing the claimed knitted wire and chainmail. However, review of the text fails to reveal any such disclosure. It merely describes material that may be used for trellis 24. Review of the remainder of DiMatteo does not reveal any disclosure therein that trellis 24 may be knitted wire or chainmail.

The Office Action fails to provide substantial evidence of the allegations relied upon. Under the Administrative Procedure Act (APA) applicable to the

Office's allegation, the standard of review applied to findings of fact is the "substantial evidence" standard. See, In re Gartside, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). See also MPEP § 2144.03 (2007). Applicant asserts the facts relied upon are not known in the art and traverses the allegation. It is not permissible for the Office to base rejections on unsupported assumptions.

The above referenced text of DiMatteo appearing in the "Detailed Description of the Invention" section provides additional details and explanation of the subject matter disclosed in comparison to the brief disclosure of the "Summary of the Invention" section relied upon in the Office Action. The Applicants explanation above and elsewhere herein should be considered the more weighty evidence since the Office is required to consider the reference as a whole. Details missing from the summary relied upon by the Office show that DiMatteo does not in fact anticipate the valve of claim 23.

At least for such reasons, claim 23 and the claims depending therefrom are patentable. Claim 32 and the claims depending therefrom set forth similar limitations and are patentable for similar reasons. Applicant requests withdrawal of the rejection in the next Office Action.

Further dealing with the specific points raised by the Examiner concerning DiMatteo, we point out that the construction disclosed in DiMatteo is fundamentally different to that of the present invention:- in DiMatteo, the valve flaps (leafs) are made from a valve leaf frame which is a frame defining the exterior edge of each valve flap. The framework is covered by a valve

leaf cover. The construction is described column 2 line 51 onwards and it is quite clear that there is absolutely no disclosure of a valve flap consisting of a flexible openwork structure of metal, where the flexible openwork structure is made of knitted wire or chainmail. The passage column 3 line 4-22 quoted by the Examiner simply reinforces the above:- the framework which forms the exterior of the valve flap has to be covered over (to make it impermeable) by cultured tissue cells as described or, as described column 2 line 51 onwards by textile such as Dacron, or polyethylene or silk.

Apparently, the Examiner is interpreting the term “flexible openwork structure” as meaning the external frame which defines the outer perimeter of the valve flap, whereas in the present application, the flexible openwork structure is the entire body of the flap itself:- there is no external framework at all forming the flap. DiMatteo in column 3, line 6-11 does propose that the valve leaf framework can be covered by a micro filter type support mesh, but this construction, i.e. a framework covered by a mesh and together forming the valve flap, is a different construction to that of the present invention, in which the valve flap includes a flexible openwork structure in the form of a knitted structure or a chainmail structure. In DiMatteo, the valve flap cannot be said to “consist of a flexible openwork structure of a medically acceptable metal coated with a degradable sealing material” because if you took the openwork structure of DiMatteo, i.e. the frame of the flap, you could not coat this with anything:- there is a empty space in the middle of the flap which has to be covered by a suitable material before it could be coated with anything.

The Examiner cites column 4, lines 33-44 as providing a basis for the flexible openwork structure being selected from knitted wire and chainmail. However, the passage cited simply describes forming a trellis which is described (column 4, line 15-32) as forming both the supporting scaffold and the valve leaf frames from a single undulating wire which is bent to form both the radially expandable scaffold portion and the radially expandable valve leaf frames. In other words, this is a proposal to form the framing part of the component (the supporting scaffold and the frames of the flaps) by one continuous length of wire bent to the necessary shape. There is no disclosure of making the actual valve flap, as a self supporting structure, from wire in the form of a knitted wire or chainmail.

It is emphasized that in all of the embodiments described in DiMatteo, an essential feature of the DiMatteo invention is a valve leaf frame (i.e. a valve flap frame), and it is clear from DiMatteo that the valve frames do not function and are not intended to function, as the whole of the valve leafs or flaps:- they are simply a supporting framework which requires covering in some way before it can perform as a valve flap. In contrast, in the present invention, the valve flaps are formed completely and entirely from a knitted wire structure or a chainmail structure, which can then be coated with a degradable sealing material. However, the coating of the flaps of the present invention with a degradable sealing material is not equivalent to providing the cover over the valve flap frames in DiMatteo:- in the present invention the degradable coating lies over the valve flap which is already present – it simply seals the minute holes between adjacent wires in the knitted or

chainmail structure. In contrast, in DiMatteo, the frames have to be covered in some way to provide the actual body of the valve flap or leaf. This is an important structural difference.

Applicant herein establishes adequate reasons supporting patentability of claims 1-7, 9-11, 14, and 23-34 and requests allowance of all pending claims in the next Office Action.

Respectfully submitted,

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